



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20530
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/688,254 | 10/13/2000 | Harry M. Meade | 10275-139001 | 9900 |

7590 05/21/2002

LOUIS MYERS
FISH & RICHARDSON P.C.
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

10

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/688,254

Applicant(s)

MEADE ET AL.

Examiner

Celine Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-10 and 12-15 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that claims 12-15 are directed to the same invention as the claims of Group I. This argument is persuasive and claims 12-15 are rejoined with Group I. Claims 11 and 16-18 are cancelled by Applicant's request. Accordingly, claims 1-10 and 12-15 are currently under examination.

Drawings

The drawings are objected to because of the informalities as indicated by Draftsperson on PTO form 948 (see attached form). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Any response to this office action which does not response to the above objections will be considered non-responsive.

Claim Objections

Applicant is advised that should claim 7 be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

Claims 1-4 and 15 are rejected under 35 U.S.C. 101 because they are not directed to statutory subject matter. It is PTO policy not to issue claims that encompass humans (see 1077 OG 24, April 21, 1987). This rejection may be overcome by inserting “non-human” before “animal”.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic system for purification of a target polypeptide comprising a transgenic mammal, does not reasonably provide enablement for said system comprising any transgenic animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The nature of the invention is either a method or a system for purification of a target polypeptide using a multivalent polypeptide produced in the milk of a transgenic animal. The state of art teaches that animal kingdom includes vertebrate and invertebrate. Within the vertebrates, they are further divided into five groups: fishes, amphibians, reptiles, birds and mammals. Only mammals produce milk. The specification fails to teach any other animals that can produce milk. However, the breath of the claim is very broad, and the claims encompass any

Art Unit: 1636

transgenic animal. Lack of guidance from the specification and teaching from prior art, one skilled in the art would have to engage in undue amount of experimentation to make/use the invention commensurate in scope with these claims, i.e. to produce a multivalent polypeptide in the "milk" of a transgenic zebra fish. Therefore, it would be remedial to amend the claims to be drawn to methods relying upon non-human transgenic mammals.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-4, the recitation of "a transgenic system for purification of a target polypeptide...comprising..." renders the claims indefinite because it is unclear whether Applicants are claiming a composition or a method. Applicants are advised to write claims in a way that clearly indicate the claimed subject matter.

Regarding claim 3, the term "binding moiety" renders the claim indefinite because it is unclear which binding moiety Applicants are referring to. Claim 1 (which claim 3 depends on) recites two "binding moieties." One that binds the bindable epitope, and the other binds the matrix. It is unclear which one of these "binding moieties" would remove the bindable epitope.

Regarding claim 4, the term "catalytic domain" renders the claim indefinite because the nature of the "catalytic domain" applicants are referring to is unknown. A "catalytic domain" is

Art Unit: 1636

the part of an enzyme that is responsible for enzymatic reaction. However, not every enzyme can remove the bindable epitope of the target polypeptide, for example, a kinase or a methylase.

Regarding claims 4-10 and 12-15, the term “transgenic multivalent binding polypeptide” renders the claim indefinite because the nature of said polypeptide is unclear. The specification defines such polypeptide is made transgenically (see page 15, lines 1-3). It is unclear whether the polypeptide is made *in vivo* by a transgenic animal or *in vitro* by a cell that normally does not express said polypeptide.

Regarding claims 5-10 and 12-15, the sentence “removing reaction mixture... the thereby obtain...” renders the claims indefinite because it is unclear what “the thereby” means within the context of the sentence.

Regarding claims 9 and 10, the term “a fragment thereof” renders the claims indefinite because it is unclear which part or fragment of “protein L” or “cellulose binding domain” Applicants are referring to. In other word, what is the size of the fragment, is it N terminal, C terminal or just a fragment in the middle?

Claim 15 recites the limitation "another transgenic animal" in line 2. However, the parent claim 12 does not recite any “transgenic animal.” There is insufficient antecedent basis for this limitation in the claim.

Claims 5-10 and 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: eluting the target polypeptide from the matrix; removing the bindable epitope from said target polypeptide.


Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
May 20, 2002


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600